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January 11, 2007

BY ELECTRONIC FILING

The Honorable Sue L. Robinson United States District Court 844 King Street Wilmington, DE 19801

Re:

Boston Scientific Corp. and Boston Scientific Scimed, Inc.

v. Conor Medsystems, Inc., 05-768-SLR (D. Del.)

Dear Chief Judge Robinson:

On January 4, 2007, Your Honor instructed BSC to provide citations supporting its request for certain of Conor's foreign regulatory filings and vendor and clinical investigator communications to test Conor's § 271(e)(1) defense. In response, BSC respectfully cites:

American Standard Inc. v. Pfizer Inc., 722 F. Supp. 86, 103 (D. Del. 1989) (holding commercial manufacture and marketing nonexempt); Ventrassist Pty Ltd. v. Heartware Inc., 377 F. Supp. 2d 1278, 1285 (S.D. Fla. 2005) (finding discovery could show conduct was nonexempt); Ortho Pharm. Corp. v. Smith, Civ. A. No. 90-0242, 1990 WL 121353, 23 (E.D. Pa. Aug. 17, 1990) (§ 271(e)(1) does not permit use for obtaining foreign premarketing approval or promotional or commercial use in U.S. or abroad) (attached as Ex. A); NeoRX Corp. v. Immunomedics, Inc., 877 F. Supp. 202, 208 (D.N.J. 1994) (denying motion for summary judgment that product manufactured in the U.S. and sent to foreign regulatory agencies was exempt); Scripps Clinic and Research Found. v. Genentech, Inc., 666 F. Supp. 1379, 1396 (N.D. Cal. 1987) (holding sale of product to supplier "clearly ... beyond the protection of 271(e)(1)"), aff'd in part and rev'd in part on other grounds, 927 F.2d 1565 (Fed. Cir. 1991); Biogen, Inc. v. Shering AG, 954 F. Supp. 391, 396–97 (D. Mass. 1996) (holding shipment of samples produced in the U.S. to foreign regulatory authorities nonexempt).

General background regarding § 271(e)(1) can be found at Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005); Eli Lilly & Co. v. Medtronic, Inc., 872 F.2d 402 (Fed. Cir. 1989); Telectronics Pacing Sys., Inc. v. Ventritex, Inc., 982 F.2d 1520 (Fed. Cir. 1992); and Intermedics. Inc. v. Ventritex Co., Inc., 991 F.2d 808 (Fed. Cir. 1993).

Respectfully submitted,

Adam W. Poff (No. 3990)

ce: Clerk of the Court
Jack B. Blumenfeld, Esq.
Jared B. Bobrow, Esq.